REMARKS

Claims 17 and 19-23 are pending and remain variously rejected under 35 U.S.C. §§ 102(a) and (b). Although the claims are not amended herein, Applicants have presented a listing of the claims above, which includes the proper status identifiers.

Applicants note with appreciation that the rejections under 35 U.S.C. § 112 have been withdrawn and that claims 19, 20, 22 and 23 are allowable.

Interview Summary

The Examiner's statement of the substance of the telephone interview conducted on August 25, 2003 is accurate.

Rejections under 35 U.S.C. § 102(a) and (b)

The Examiner has rejected claims 17 and 21 under 35 U.S.C. § 102 as allegedly anticipated by Glasgow *et al.* (*Virology* 1991, Vol. 185, pp. 741-748) or alternatively, as allegedly anticipated by Glomb-Reinmund *et al.* (*J. Virol.* 1998, Vol. 72, pp. 4281-4287). Although the Examiner acknowledges that neither references teaches alphavirus particles that infect human dendritic cells (DCs), it is maintained that because the alphaviruses contain mutations are in the same region as claimed by Applicants, the molecules described in the references would **inherently** exhibit the same biological function of human DC tropism as the molecules of claims 17 and 21. (Final Office Action, paragraphs 4 and 8).

Applicants traverse the rejection and supporting remarks.

In order to be an anticipatory reference, the reference cited by the Office must disclose each and every element of the claims, including each and every functional or biological limitation. *See, e.g., Hybritech v. Monoclonal Antibodies,* 231 USPQ 81 (Fed. Cir. 1986); M.P.E.P § 2173.05(g) Functional Limitations, Eighth Edition. Moreover, the single source must disclose all of the claimed elements arranged as in the claims. *See, e.g., Richardson v. Suzuki Motor Co.,* 9 USPQ2d 1913 (Fed. Cir. 1989). Simply put, the law requires identity as between the prior art disclosure and the invention. *See, e.g., Kalman v. Kimberly-Clark Corp.* 218 USPQ 781 (Fed. Cir. 1983), *cert. denied,* 484 US 1007 (1988). Further, to support an anticipation rejection based on inherency, the Office must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings of the reference. *See, e.g., Ex parte Levy,* 17 USPQ2d 1461, 1464 (BPAI 1990). Inherency cannot be established by probabilities or possibilities. *See, e.g., Continental Ca Co. USA, Inc. v. Monsanto Co.* 20 USPQ2d 1746, 1749

(Fed. Cir. 1987). Thus, the references must teach all elements of the claims, explicitly or inherently, including functional limitations such as biological function.

Applicants submit that the Office has not met its burden of establishing a *prima facie* case of anticipation because Glasgow and Glomb-Reinmund do not inherently disclose the required human DC tropism of the recombinant alphavirus molecules of claims 17 and 21. As noted above, it is well established that, under the doctrine of inherency, a reference can anticipate a claim if and only if the missing element is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676 (Fed. Cir. 2002) citing *Cont'l Can Co. v. Monsanto Co.*, 20 USPQ2d 1746 (Fed. Cir. 1991). In other words, inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

In the pending application, the molecules of claims 17 and 21 must not only be recombinant alphavirus particles having a mutation in the specified region, they must also infect human dendritic cells. Thus, the question is not whether Glasgow and Glomb-Reinmund disclose molecules that have mutations in the specified regions E2, but whether one skilled in the art would read these references as necessarily disclosing that these molecules infect human dendritic cells. In point of fact, there is absolutely no evidence in the record to support a finding that one skilled in the art would so read Glasgow and Glomb-Reinmund. To the limited extent that Glasgow or Glomb-Reinmund disclose mutant alphaviruses, there is no indication as to whether these molecules infect any dendritic cells, let alone human DCs as claimed. Both references studied alphaviruses in rodent cells, namely Balb/C mice in Glasgow and baby hamster kidney cells (BHK cells) in Glomb-Reinmund. There is no disclosure in either reference regarding human cells and certainly no disclosure regarding human dendritic cells. Furthermore, the record is clear that alphaviruses exhibit different tropism for human as compared to rodent DCs. *See, e.g.*, page 25, lines 11-13 of the specification. In view of the established differences between infection of human and rodent cells, it is plain that, even if the references were to suggest that the mutant alphaviruses infected the tested rodent cells (which they do not), inherency is not present as to the claimed human DC-tropic cells. Thus, because the concept of a recombinant, mutated alphavirus that infects human DCs is entirely absent from either reference and cannot inevitably flow from either disclosure, Glasgow or Glomb-Reinmund do not in any way inherently disclose the molecules of claims 17 and 21.

The anticipation rejections based on alleged inherency are also improper because no evidence has been offered by the Office supporting the assertion that any and all alphavirus particles having mutations in the claimed region would necessarily infect human dendritic cells. As the Board of Patent Appeals and Interferences and Federal Circuit have repeatedly established, "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic" of the reference. *Ex parte Skinner,* 2 USPQ2d 1788 (BPAI 1986), emphasis added. The Office has provided no such evidence or reasoning, but, instead, has merely asserted that any reference related to the mutated alphavirus particles inherently discloses the particularly claimed invention of claims 17 and 21. In fact, Glasgow and Glomb-Reinmund fail entirely to describe or demonstrate molecules that infect human DCs. Neither reference discloses or suggests that the molecules may infect human DCs and, unlike Applicants, neither reference even describes experiments in human cells or notes the differences between human and mouse DC tropism. (*See, also,* page 25, lines 11-13 of the specification). In the absence of any evidence supporting inherency and the abundance of evidence against inherency, Applicants submit that the rejection is improper and should be withdrawn. In the event that the Examiner continues to maintain these unsupported rejections, Applicants request, pursuant to 37 C.F.R. § 1.104(d)(2), that the Examiner support this rejection with an affidavit.

In sum, because Glasgow and Glomb-Reinmund fail to necessarily disclose or describe the characteristics (*e.g.,* human DC-tropism) of the molecules of claims 17 and 21, as recited in the claims, these references do not anticipate any of the pending claims and withdrawal of the remaining rejections is in order.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Please direct further communication regarding this application to:

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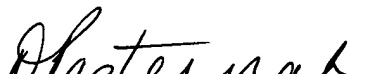
Respectfully submitted,

Date: November 12, 2003

By: 

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